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# Summary of the June 20, 2003 BPAC

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# BPAC Summary

BPAC June 13, 2002

- Should FDA develop standards for recovered plasma?
  - Unanimously voted yes
  - Additional recommendations:
    - Come up with an alternative name
    - Develop strategy to allow apheresis plasma from Whole Blood donors to be used for further manufacture
    - Distinguish the component from Source Plasma



# BPAC Summary

To address the alternative name issue FDA proposed:

- “Component Plasma”



## BPAC Summary

**To address the “apheresis from Whole Blood donor” issue FDA proposed:**

- Defining the component as “plasma that is collected manually or by apheresis, either separately or concurrently with other blood components, from donors who meet all Whole Blood donor suitability requirements.”



# BPAC Summary

**To address the distinction from Source Plasma issue FDA proposed:**

- Moving the requirement to freeze immediately after collection into the definition of Source Plasma



# BPAC Summary

FDA proposed additional issues:

- Should a “Time to Freezing” standard be defined for plasma used to manufacture labile derivatives?
- 10 yr Expiration date?





# BPAC Summary

Industry presentations suggested:

- License recovered plasma
- Harmonization with EU standards
- Freezing temperatures consistent with FFP
- Rename “Plasma for Manufacture”
- 2-3 year expiration
- No specific time to freezing



# BPAC Summary

Committee recommendations:

- “Component Plasma” - possible name
- Different name for plasma for manufacture into non-injectable products
- Not enough data available to comment on changing the definition of SP to include freezing immediately after collection





# BPAC Summary

## Committee recommendations:

- Not enough data available to decide on appropriate temperatures or dating periods
- Not enough data available to comment on time to freezing as a criteria for manufacture in labile derivatives
- Have a workshop to gather needed data